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# Physical activity counseling in overweight and obese primary care patients: Outcomes of the VA-STRIDE randomized controlled trial

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#### ABSTRACT

The purpose of this 2-arm randomized clinical trial was to evaluate the effectiveness of a 12-month, expert system-based, print-delivered physical activity intervention in a primary care Veteran population in Pittsburgh, Pennsylvania.

Participants were not excluded for many health conditions that typically are exclusionary criteria in physical activity trials. The primary outcome measures were physical activity reported using the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire and an accelerometer-based activity assessment at baseline, 6, and 12 months.

Of the 232 Veterans enrolled in the study, 208 (89.7%) were retained at the 6-month follow-up and 203 (87.5%) were retained at 12 months. Compared to the attention control, intervention participants had significantly increased odds of meeting the U.S. recommended guideline of  $\geq$  150 min/week of at least moderate-intensity physical activity at 12 months for the modified CHAMPS (odds ratio [OR] = 2.86; 95% CI: 1.03–7.96; p = 0.04) but not at 6 months (OR = 1.54; 95% CI: 0.56–4.23; p = 0.40). Based on accelerometer data, intervention participants had significantly increased odds of meeting  $\geq$  150 min/week of moderate-equivalent physical activity at 6 months (OR = 6.26; 95% CI: 1.26–31.22; p = 0.03) and borderline significantly increased odds at 12 months (OR = 4.73; 95% CI: 0.98–22.76; p = 0.053).

An expert system physical activity counseling intervention can increase or sustain the proportion of Veterans in primary care meeting current recommendations for moderate-intensity physical activity.

Trial Registration Clinical trials.gov identifier: NCT00731094 URL: http://www.clinicaltrials.gov/ct2/show/NCT00731094.

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# Introduction

The 1995 Centers for Disease Control and Prevention and the American College of Sports Medicine joint summary statement on the health benefits of physical activity recommended at least 30 min of moderate to vigorous intensity aerobic physical activity on most days of the week (Pate et al., 1995). In 2000, the U.S. Department of Health and Human Services (DHHS) identified increasing the proportion of adults who meet this physical activity recommendation as a Healthy People 2010 goal (United States Department of Health Human Services,

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2000). In 2008, DHHS released the national Physical Activity Guidelines (United States Department of Health and Human Services, 2008) that recommended at least 150 min per week of moderate to vigorous intensity aerobic physical activity.

Despite consistent attention and recommendations since the 1990s, a majority of U.S. adults persistently fail to meet the recommended levels of physical activity (Blackwell et al., 2014; Centers for Disease Control and Prevention (U.S.), 2007; Centers for Disease Control and Prevention (U.S.), 2001). Among Veterans, an analysis of 2000 Behavioral Risk Factor Surveillance System data showed Veterans to be as sedentary as the general population, with 44% being overweight and 25% obese; among obese Veterans, 59% were inactive and only 16% adhered to recommended levels of physical activity (Wang et al., 2005).

Numerous studies have shown face-to-face physical activity interventions to be efficacious for engaging participants in a more active

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lifestyle. However, practical barriers (e.g., time, cost, and the need to travel to a central location) limit the reach of such interventions and reduce their public health impact. Literature reviews have shown that home-based interventions may be more effective than center-based interventions (Hillsdon & Thorogood, 1996) and that interventions not requiring face-to-face contact have larger effect sizes (Dishman & Buckworth, 1996). Based on these findings, Marcus and colleagues developed an expert system that generates theory-based motivationally tailored physical activity counseling messages (Marcus et al., 1998; Bock et al., 2001; King et al., 1991, 1995). Using that system, these investigators evaluated the efficacy of two counseling delivery approaches (print messages sent via postal mail versus messages discussed via telephone) to engage healthy adults in a home-based program of physical activity in Project STRIDE (Marcus et al., 2007a, b). Compared to participants randomized to an attention control arm, both intervention arms demonstrated significant increases in physical activity at 6 months. At 12 months, physical activity declined in the telephone arm but continued to increase in the print-mail arm. The print intervention also was more cost-effective than the telephone approach (Sevick et al., 2007).

In the VA-STRIDE study, we evaluated the effectiveness of the Project STRIDE print intervention among Veterans recruited from a primary care setting. The primary hypothesis of VA-STRIDE is that participants randomized to the print intervention arm would be more likely than attention control arm participants to meet the U.S. recommended physical activity target of at least 150 min per week of moderate-intensity physical activity.

#### Methods

#### Design

VA-STRIDE was a randomized controlled trial among Veterans receiving routine care through the VA Pittsburgh Healthcare System (VAPHS) University Drive Campus (UD) Primary Care Clinic. Veterans enrolled in the study were randomized to either a physical activity intervention arm or an attention control arm. Measurements occurred at baseline, 6 months, and 12 months. The study was reviewed and approved by the VAPHS Institutional Review Board.

#### Sample

To be eligible for the study, participants were required to: (1) have had at least one primary care visit at the VAPHS UD clinic in the 12 months prior to screening, (2) be at least 18 years old at the time of enrollment, and (3) be overweight or obese (i.e., body mass index  $(BMI) \ge 25 \text{ kg/m}^2$ ) at the most recent primary care visit. Excluded from the study were Veterans with existing ICD-9 codes for psychoses (codes 290-299), alcohol or drug dependence (codes 303 and 304), intellectual disability (codes 317-319), unstable angina (code 411.1), pulmonary hypertension (codes 416.0 and 416.8), spinal cord injuries (codes 806 and 952), lack of housing (code V60.0), long-term oxygen therapy (code V46.2), or wheelchairs (code V53.8). Additional exclusion criteria included need of an assistive walking device (e.g., cane or walker), inability to walk at least 120 yards unassisted, being non-Englishspeaking, reading below the 7th grade level, living in an institutional setting, planning to move out of the VAPHS service area in the next 12 months, employment by VAPHS, or unwillingness to adhere to the study protocol.

An electronic sampling frame was developed using the Veterans Health Information Systems and Technology Architecture (VistA) data files, which include clinical information abstracted from the computerized medical records of Veterans receiving primary care at VAPHS UD. Subject-specific ICD-9 codes were used to identify potentially eligible participants who had an upcoming visit with their primary care provider (PCP). During that scheduled visit, the PCP evaluated each potentially eligible Veteran for their ability to safely participate in unsupervised

moderate-intensity physical activity, specified any required exercise precautions, and requested the Veteran's permission to be contacted by study staff to discuss possible enrollment (Hawkins et al., 2014).

Remaining eligibility and safety criteria were evaluated during a subsequent telephone screen conducted by study staff. Baseline physical activity was ascertained using a 2-part question. Veterans were asked if, during a typical week, they engaged in any moderate-intensity aerobic physical activity of at least 10-min duration and if so, whether they engaged in such activity for at least 60 min/week; those who responded affirmatively were ineligible. We also excluded Veterans participating in other clinical studies that would be expected to impact the primary VA-STRIDE study outcome of physical activity.

MOVE! is a national weight management program supported by the VA's National Center for Health Promotion and Disease Prevention. Veterans are screened annually for obesity and referred to MOVE! programs that vary by VA facility. At the time of the VA-STRIDE study MOVE! program options within the VAPHS included weekly group meetings, and teleconferencing. While physical activity is addressed in MOVE! the primary goal of the program is weight management. MOVE! participants were not excluded from the study as the program is considered standard care within the VA Healthcare System. Additional details on the recruitment and enrollment process for this study are provided elsewhere (Hawkins et al., 2014).

#### **Procedures**

#### Baseline assessment

Signed informed consent was obtained from eligible Veterans during their baseline study visit, at which time demographic, clinical, and self-reported physical activity data were collected. Physical activity also was measured using accelerometers during the week following the baseline visit, after which participants were randomized. Participants were given \$25.00 for the time and travel expenses associated with this baseline visit.

# Randomization and orientation

Participants attended a 60-min orientation session about one week after their baseline assessment, at which time they were informed of their randomized treatment assignment and received initial counseling relevant to their treatment arm.

Those randomized to the intervention arm received individually tailored physical activity counseling based on medical conditions identified in their medical record and their baseline assessment. This session included guided goal setting to gradually increase moderate-intensity aerobic physical activity to at least 150 min/week. For those randomized to the attention control, the orientation session involved generalized healthy lifestyle counseling that included recommendations regarding cancer screening, cholesterol, nutrition, balancing calorie intake and energy expenditure, alcohol consumption, stress and relaxation, and sleep. To minimize cross-over effects, orientation sessions were delivered by two different study staff. Participants in both arms were given \$15.00 for the time and expense associated with their orientation session.

#### Intervention

Subsequent to the initial orientation session, the intervention group received 12 months of expert system feedback counseling, delivered via postal mail, in parallel with 12 months of routine primary care. Using the same approach as Project STRIDE (Marcus et al., 2007a), participants were mailed a Physical Activity Questionnaire (PAQ) monthly during months 1–6 and bimonthly during months 7–12. PAQs were completed, returned, and scanned into an expert system to produce theory-based individualized feedback reports. Printed feedback reports were mailed back to participants, along with physical activity self-help booklets matched to the Veteran's stage of motivational readiness and newsletters with suggestions for increasing physical activity. Fourteen feedback mailings were sent to participants on the following schedule: weekly

during month 1, bi-weekly for months 2 and 3, monthly for months 4 through 6, and then bi-monthly for the final 6 months of the study.

The individualized feedback reports generated by the expert system included preplanned counseling messages that targeted deficiencies and reinforced successful efforts based on data derived from the PAQs. The messages provided three types of feedback: (1) motivational feedback regarding the participant's current stage of readiness for physical activity adoption; (2) normative feedback that included assessments of (a) self-efficacy or confidence in their ability to engage in physical activity, (b) decisional balance or the pros and cons of physical activity, (c) behavioral and cognitive processes associated with physical activity, and (d) the Veteran's profile compared to those who had successfully adopted and sustained physical activity; and (3) ipsative feedback, or feedback on progress made since the last feedback report. Ipsative feedback included information regarding change in motivation, confidence, decisional balance, thoughts and behaviors, and time devoted to physical activity. Expert-system feedback reports were used to encourage Veterans to increase their level of physical activity to at least 150 min of moderate-intensity exercise each week, distributed in increments of 30 min a day, 5 or more days a week, in at least 10 min episodes.

#### Attention control

Attention control participants received a series of wellness newsletters over the 12 months subsequent to the initial orientation session, in parallel with 12 months of routine primary care. The newsletters did not contain specific information about physical activity. To equalize attention, the planned frequency of contacts, including scheduled mailings, was the same for the intervention and control arms.

#### Follow-up measurement

Follow-up measurement visits were conducted at 6 and 12 months after the baseline assessment at the VHA. Due to staffing limitations, study staff involved in measurement visits could not always be blinded to group assignment. At each measurement visit, participants were given \$25.00 for their time and travel expenses.

#### Measures

#### Physical activity

Physical activity was quantified at the baseline and follow-up visits using a modified version of the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire (Stewart et al., 2001) and an accelerometer (Model GT3X; ActiGraph, Pensacola, FL). On the original version of CHAMPS, respondents report the number of times they engaged in 40 different physical activities in a typical week during the past 4 weeks, and the corresponding time spent, quantified in broad categories (e.g., <1 h, 1–2.5 h, 3–4.5 h. 9 or more hours) (Stewart et al., 2001). We modified the CHAMPS response options to collect the actual number of hours and minutes devoted to each reported activity that week, and converted all time estimates to minutes.

Participants were provided an accelerometer at each measurement visit, and instructed to wear it during their waking hours for the next 7 days and return it to the investigators via postal mail. Using previously validated accelerometer cut-points (Sasaki et al., 2011), moderate-intensity aerobic physical activity was classified as 2690–6166 counts and vigorous-intensity aerobic physical activity as >6167 counts. To assess physical activity by DHHS guidelines (≥150 min/week of moderate, ≥75 min/week of vigorous, or a combination of both with 1 min of vigorous activity equal to 2 min of moderate activity) (United States Department of Health and Human Services, 2008), we defined moderate-equivalent activity minutes as the sum of the moderate-intensity activity minutes plus 2 times the vigorous-intensity activity minutes. This sum was divided by the number of days of measurement to define average minutes per day of moderate-equivalent physical activity, and this average was multiplied by 7 to estimate total minutes per week.

Participant health and sociodemographic characteristics

Baseline weight (in kg) was assessed using a body composition analyzer (Model TBF-200A; Tanita Corporation of America, Arlington Heights, IL). Height was abstracted from the medical record. Blood pressure was obtained using a Doppler cuff (LifeSource Model UA-767 Plus; A&D Medical, San Jose, CA) with the Veteran in a seated position. Self-reported age, race, sex, ethnicity, marital status, education, employment, income, medical conditions, and participation in the VA MOVE! program were obtained via questionnaire.

#### Analysis

Baseline characteristics were compared between the two study arms using Pearson chi-squared, Fisher's exact, or Student's t tests, as appropriate. Profile plots were used to summarize the proportions of Veterans engaged in the recommended  $\geq$  150 min of at least moderate-intensity aerobic physical activity per week for the modified CHAMPS and  $\geq$  150 min of moderate-equivalent aerobic physical activity per week for the accelerometer data at baseline, 6 months, and 12 months.

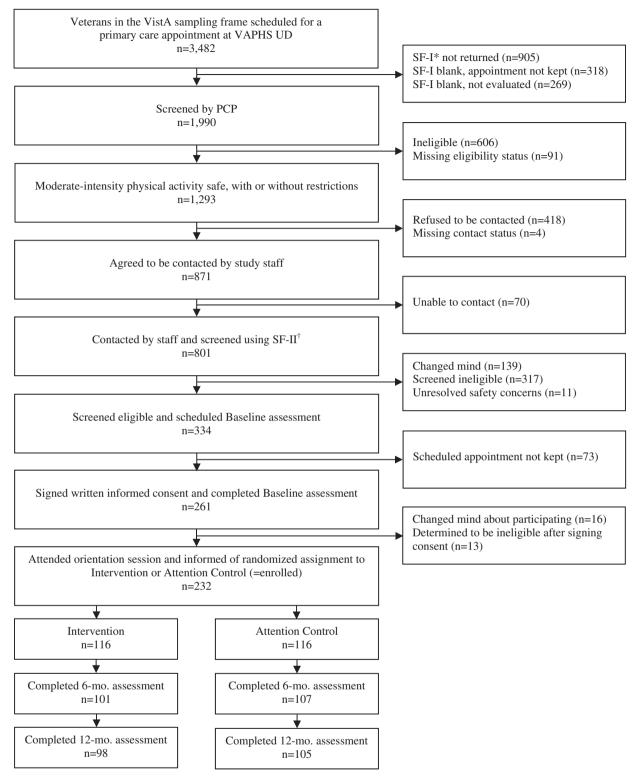
Conditional logistic regression was used to model within-person change in the probability of meeting the recommended  $\geq 150$  min/week of aerobic physical activity over time, based on separate models for the modified CHAMPS and accelerometer data. The models included two dummy variables for time (i.e., 6 months and 12 months), and two dummy variables for the treatment group by time interactions that quantify the intervention effect. The statistical significance of main effects of time and the treatment by time interactions was assessed using Wald statistics, with p-values < 0.05 considered to be statistically significant.

Preliminary analysis indicated missing or unreliable accelerometer data for 23.5% of participants at 6 months and 27.5% at 12 months. Missing accelerometer data occurred when the device was not returned to the study team, and unreliable data occurred when the device was not worn for a sufficient amount of time to provide a reliable estimate of physical activity. Based on prior validation (Trost et al., 2005), observations with at least 10 h of wear time per day for at least 3 days were included in the primary analysis. In sensitivity analyses, we assessed the predictors of missing data using random effects logistic regression, and conducted a subgroup analysis of the modified CHAMPS data for those who had accelerometer measurements at the same follow-up time. We also included the 58 accelerometer observations deemed unreliable.

### Results

Of the 3482 potentially eligible Veterans who were scheduled for an appointment during the recruitment period (June 2010–March 2013), 1990 were screened by their PCPs and moderate-intensity aerobic physical activity was deemed to be safe for 1293 (65.0% of those screened; Fig. 1). Of the 871 Veterans who agreed to be contacted by study staff, 232 enrolled in this study, 208 (89.7% of study participants) completed the 6-month assessment and 203 (87.5% of study participants) completed the 12-month assessment.

VA-STRIDE participants were primarily male, non-Hispanic White individuals (Table 1). Nearly half were retired and about half were married or partnered. About one-third had no more than a high school education, and about half reported a household income of <\$30,000/year. Few VA-STRIDE participants reported participation in the VA-MOVE! program, with relatively higher participation in the attention control arm (13 control compared to 3 intervention participants). Over three quarters of the participants had 2 or more health conditions; the most prevalent conditions in both arms were hypertension, arthritis, diabetes, and emotional problems, depression, or anxiety. Participants were middle aged and about 41% were obese. Other than participation in the VA-MOVE program, baseline characteristics did not differ significantly between the two study arms.



<sup>\*</sup>SF-I denotes Screening Form I (completed by PCP).

Fig. 1. VA-STRIDE CONSORT diagram (June 2010–March 2013, in Pittsburgh, Pennsylvania).

Fig. 2.A. and B. show the time-specific physical activity outcomes by treatment arm. The modified CHAMPS data show consistent increases in the proportion of Veterans in the intervention arm meeting physical activity recommendations at 6 and 12 months, and improvements at 6 months that are not sustained at 12 months in the attention control

arm. For the accelerometer data, the proportion of Veterans in the intervention arm who met recommendations remained relatively flat, while physical activity in the attention control arm decreased over time.

Based on the conditional logistic regression models (Table 2), relative to the attention control, participants in the intervention arm had

<sup>&</sup>lt;sup>†</sup>SF-II denotes Screening Form II (completed by study staff).

**Table 1**Baseline characteristics of VA-STRIDE participants by treatment arm, in Pittsburgh, Pennsylvania, June 2010–March 2013.

Characteristic	Intervention  N = 116		Attention control $N = 116$		p-Value
	n	%	n	%	
Sex (male)	96	82.8	96	82.8	>0.99
Hispanic					0.72*,†
Yes	4	3.5	3	2.6	
No	111	95.7	113	97.4	
Missing	1	0.9	0	0.0	
Race					0.91*.†
Black or African American	28	24.1	26	22.4	
White	86	74.1	87	75.0	
Multi-race	1	0.9	2	1.7	
Missing	1	0.9	1	0.9	0.20*
Employed  Full time (part time)	34	29.3	26	31.0	0.20*
Full time/part time Unemployed and looking for work	7	6.0	36 9	7.8	
Unemployed and looking for work Disabled/unable to work	21	18.1	10	8.6	
Retired	52	44.8	59	50.9	
Missing	2	1.7	2	1.7	
Married/partnered	49	42.2	55	47.4	0.43
Education, highest grade completed	13	14,4	33	17,-1	CF.0
Less than high school graduate	11	9.5	5	4.3	
Competed high school or general equivalency diploma (GED)	35	30.2	33	28.5	
Some college, associate degree, or completed technical school	47	40.5	54	46.5	
Completed college or more	23	19.8	24	20.7	0.42
Income					0.88*
<\$10,000	10	8.6	10	8.6	
\$10,000-\$29,999	48	41.4	52	44.8	
\$30,000-\$49,999	26	22.4	26	22.4	
>=\$50,000	18	15.5	18	15.5	
Missing	14	12.1	10	8.6	
Current participant of the VA MOVE! program					0.01*
Yes	3	2.6	13	11.2	
No	110	94.8	96	82.8	
Missing	3	2.6	7	6.0	
Number of comorbid conditions					
0	8	6.9	5	4.3	0.60
1	16	13.8	24	20.7	
2	32	27.6	28	24.1	
3	23	19.8	25	21.6	
4 or more	37	31.9	34	29.3	
Comorbid conditions	11	0.5	7	6.0	0.22
Angina	11	9.5	7	6.0	0.33
Arthritis	64 22	55.2 19.0 <sup>‡</sup>	60	51.7	0.60 0.27*
Cancer Congestive heart failure	4	3.5	16 6	13.8 5.2	0.27
Chronic pain syndrome	13	11.2	11	9.5	0.52
Diabetes	38	32.8	36	31.0	0.78
Emotional problem, depression, or anxiety	42	36.2	36	31.0	0.40
Hypertension	86	74.1	79	68.1	0.31
Lung disease, emphysema, asthma, or bronchitis	18	15.5	26	22.4	0.18
Myocardial infarction	13	11.2	20	17.2	0.19
Osteoporosis	4	3.5	5	4.3 <sup>‡</sup>	>0.99*,
Parkinson's disease	2	1.7	0	0.0	$0.50^{2}$
Stroke	8	6.9	11	9.5	0.47
BMI	55	47.4	40	34.5	0.39
<30 kg/m <sup>2</sup>	37	31.9	46	39.6	
30–35 kg/m <sup>2</sup>	19	16.4	21	18.1	
35–40 kg/m <sup>2</sup>	5	4.4	9	7.8	
≥40 kg/m <sup>2</sup>					
	Mean	SD	Mean	SD	
Age (years)	63.7	12.5	62.6	13.2	0.52
BMI	31.1	4.7	32.2	5.0	0.08
Systolic blood pressure (mmHg)	126.1	17.8	126.1	14.2	>0.99
Diastolic blood pressure (mmHg)	73.1	9.7	74.1	9.5	0.42

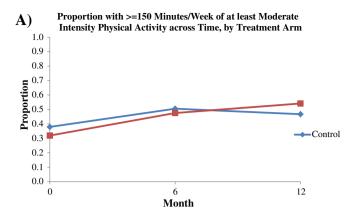
<sup>\*</sup> Test excludes "missing" category.

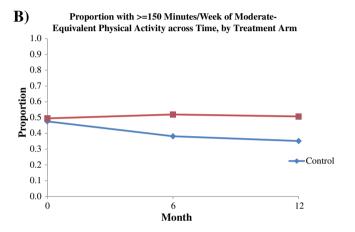
significantly higher odds of meeting the U.S. recommended  $\geq$  150 min/week of at least moderate-intensity aerobic physical activity at 12 months for the modified CHAMPS (odds ratio (OR) = 2.86; 95% CI: 1.03–7.96; p = 0.04) but not at 6 months (OR = 1.54; 95% CI: 0.56–4.23; p =

0.40). For the accelerometer, compared to the attention controls, intervention participants had significantly higher odds of  $\geq$ 150 min/week of moderate-equivalent aerobic physical activity at 6 months (OR = 6.26; 95% CI: 1.26–31.22; p = 0.03), and borderline significantly increased

<sup>†</sup> Fisher exact test was used because of small sample size.

<sup>&</sup>lt;sup>‡</sup> Missing value for one participant.





**Fig. 2.** A. Modified CHAMPS by treatment arm in Pittsburgh, Pennsylvania, June 2010–March 2013. B. Accelerometer-based Physical Activity by treatment arm in Pittsburgh, Pennsylvania, June 2010–March 2013.

odds at 12 months (OR = 4.73; 95% CI: 0.98–22.76; p=0.053). However, the CIs are quite wide. The time trends in the attention control arm were not statistically significant for either the CHAMPS or the accelerometer data (p=0.21 for. the CHAMPS and p=0.11 for the accelerometer based on 2 df Wald tests), although the decline at 12 months relative to baseline is of borderline statistical significance for the accelerometer data.

In the intervention arm, 83.6% of participants completed the accelerometer assessment at baseline, 49.1% had complete data for all 3 time points, 18.1% had data at baseline and 1 follow-up time point, and 32.8% had insufficient data for analysis, including 8.6% with no accelerometer data at all. A similar pattern was observed in the attention control arm: 88.8% completed the accelerometer assessment at baseline, 51.0% had complete data at all 3 time points, 21.6% had data at baseline and 1 follow-up time point, and 27.6% had insufficient data for analysis, including 6.9% with no accelerometer data at all. The probability of

missing data increased over time (p < 0.001), decreased with age (p < 0.001), and did not differ significantly by treatment arm (p = 0.53). In sensitivity analyses of the modified CHAMPS data, estimated ORs for those participants with both CHAMPS and corresponding accelerometer data were qualitatively similar to those for the total sample, i.e., non-significantly elevated at 6 months and significantly elevated at 12 months. The ORs of meeting the U.S. recommended  $\geq$  150 min/week of at least moderate-intensity aerobic physical activity for those with concurrent CHAMPS and accelerometer data were 1.66 (95% CI: 0.48–5.78, p = 0.43) at 6 months and 4.08 (95% CI: 1.15–14.48, p = 0.03) at 12 months.

The intervention effects in Table 2 were attenuated slightly when the 58 "unreliable" accelerometer observations were included. The ORs of meeting the U.S. recommended  $\geq 150$  min/week of at least moderate-intensity aerobic physical activity were 4.22 (95% CI: 0.94–18.88, p = 0.06) at 6 months and 3.40 (95% CI: 0.84–13.67, p = 0.09) at 12 months.

#### Discussion

Based on a review of 74 primary care relevant trials (Lin et al., 2014), in 2014 the U.S. Preventive Services Task Force (USPSTF) released the official statement that: "The USPSTF recommends offering or referring adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention." (LeFevre, 2014) However, systematic reviews indicate that only about 40% of US physicians regularly engage in regular physical activity counseling (VanWormer et al., 2009), and that primary care providers perceive numerous barriers to physical activity counseling including uncertainty about effectiveness, discomfort in counseling patients, and lack of time, training, and reimbursement (Hebert et al., 2012).

In VA-STRIDE, an expert system that did not rely on busy providers to deliver counseling, appeared to promote or at least maintain physical activity in older adult Veterans. While CHAMPS and the accelerometer quantify physical activity using different metrics (i.e., minutes of at least moderate-intensity and minutes of moderate-equivalent physical activity, respectively), both measures suggest that the intervention may have an impact on behavior. The modified CHAMPS data showed that intervention participants were nearly three times as likely as attention control participants to report ≥ 150 min/week of at least moderate-intensity aerobic physical activity at 12 months. Accelerometer data from the intervention group demonstrated a slight increase in the proportion of physically active participants at 6 months, which was sustained at 12 months. The attention control group demonstrated reductions in the proportions of participants meeting the physical activity recommendations over time.

Several recent reports comparing self-reported physical activity to accelerometer data show that adults over-report time devoted to physical activity and under-report time spent in sedentary behavior (Palta et al., 2015; Drystad et al., 2014; Downs et al., 2014; Yates et al., 2015; Yu et al., 2015). Because of the potential of respondent bias,

**Table 2**Estimated odds ratio of achieving ≥150 min/week of physical activity, based on conditional logistic regression models, in Pittsburgh, Pennsylvania, June 2010–March 2013.

Level of physical activity	Attention control at 6 months			Intervention vs. attention control at 12 months	
≥150 min/week	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)	
	p-Value	p-Value	p-Value	p-Value	
At least moderate-intensity activity (Modified CHAMPS) Moderate-equivalent physical activity (Accelerometer)	1.78 (0.92, 3.45) 0.09 0.47 (0.17, 1.31) 0.15	1.50 (0.78, 2.87) 0.23 0.33 (0.11, 1.03) 0.057	1.54 (0.56, 4.23) 0.40 6.26 (1.26, 31.22) 0.03	2.86 (1.03, 7.96) 0.04 4.73 (0.98, 22.76) 0.053	

accelerometer data usually are considered to have greater validity than self-reported physical activity. One might have more confidence concluding that the VA-STRIDE intervention prevented physical activity decline than increased it, despite the moderate amount of missing accelerometer data. These results are promising because preventing decline in physical activity in a sample of older, overweight or obese, sedentary adults is important for preventing additional weight gain and obesity-related medical conditions (Wareham et al., 2005; Shiroma & Lee, 2010) and preserving cognitive (Kirk-Sanchez & McGough, 2014) and physical function (Chang et al., 2013).

The original Project STRIDE intervention was shown to be efficacious in increasing physical activity (based on the 7-day PAR interview) in a healthy, community-derived sample of participants who were primarily White, female, college educated young adults. Because STRIDE and VA-STRIDE used different measures of physical activity, direct comparisons are not possible. However, our clinically-derived sample of older Veterans was primarily male and more racially diverse, with fewer years of education and fewer economic resources than participants in Project STRIDE. Also, a substantial proportion of VA-STRIDE participants had multiple medical conditions, including many that would have resulted in exclusion from Project STRIDE (e.g., BMI > 35, hypertension, heart disease, stroke, and lung disease).

Five recently completed randomized clinical trials of physical activity interventions in U.S. Veterans were reported in the literature (Fetzner & Asmundson, 2014; Goldberg et al., 2013; Krein et al., 2013; Moy et al., 2015; Morey et al., 2009). Four studies targeted Veterans with specific illnesses or conditions including younger Veterans with post traumatic stress disorder (Fetzner & Asmundson, 2014), and those with serious mental illness (Goldberg et al., 2013), chronic back pain (Krein et al., 2013), and COPD (Moy et al., 2015). Morey et al. targeted primary care Veterans, but restricted their sample to those who were 70 years old and older (Morey et al., 2009) with the goal of preserving physical function. One study evaluated MOVE! in terms of weight gain in Veterans pre- and post-enrollment in the program, but did not report changes in physical activity (Romanova et al., 2013). It is difficult to draw conclusions about the performance of our approach relative to these prior studies because none evaluated the intervention in terms of efficacy or effectiveness for engaging a general primary care Veteran population in 150 min/week or more of at least moderate intensity physical activity.

Muller and Khoo conducted a recent meta-analysis of 16 non-face-to-face physical activity interventions in older adults (Muller & Khoo, 2014). Similar to VA-STRIDE, all 16 used theory-based intervention approaches, 15 tailored counseling messages to the performance of the participant, and 11 delivered the intervention via print or phone. Only 1 of the 14 studies that reported significant increases in physical activity measured physical activity using accelerometers. That study used accelerometers in a randomly selected subset of 56 participants (25.7% of the total sample), and reported that at 6 months, intervention participants spent significantly more time engaged in moderate or greater physical activity than did control participants ( $M=112.5\ min/week$ ,  $SD=118.3\ and\ M=36.8\ min/week$ , SD=35.2; p=0.004, respectively) (King et al., 2007).

Different screening definitions of sedentary behavior were used in Project STRIDE and VA-STRIDE. Project STRIDE required 20–30 min to administer the 7-day PAR, and excluded those who engaged in 90 min/week or more of the target behavior. Because the goal of VA-STRIDE was to implement the study protocol in a way that could easily be integrated into routine care, the VA-STRIDE two-part screening question required less than 1 min to administer. Although we set a lower exclusion threshold for physical activity (i.e., 60 min/week) than was used in Project STRIDE, the shortened screening procedure did not identify some Veterans who met national targets of ≥150 min/week of at least moderate-intensity physical activity based on their subsequent baseline physical activity measurements. It also is possible that some VA-STRIDE participants

increased their level of physical activity in the week between screening and baseline measurement.

The strengths of the VA-STRIDE study include the randomized design with a control group receiving equivalent attention, use of VistA to establish the sampling frame, performance in a clinical sample including individuals typically excluded from physical activity trials, and measurement of physical activity using both self-report and more objective accelerometer data. The study is limited by the moderate amount of missing accelerometer data. Although the analysis included all reliable data to the extent possible, we could not identify sufficiently strong predictors of accelerometer measurements to conduct credible multiple imputation. Also, it was not possible to blind staff involved in measurement visits to randomization assignment. While CHAMPS and accelerometer measurements were not staff-administered, the possibility of measurement bias cannot be eliminated. Accelerometer-based physical activity outcomes may have been influenced by reactivity, albeit we have no reason to believe that such bias would differ between the randomization groups. Finally, Veterans drawn from a single clinical facility may not be representative of all potentially eligible Veterans or primary care patients.

#### Conclusion

In conclusion, an expert-based physical activity counseling intervention successfully increased the odds of meeting the U.S. recommended levels for aerobic physical activity in older primary care Veterans with health conditions that typically are exclusionary criteria in physical activity trials. Benefits were observed in terms of both self-reported minutes of at least moderate-intensity activity and accelerometer measurements of minutes of moderate-equivalent physical activity.

#### **Conflict of interest**

The authors declare that they have no conflicts of interest.

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